TESTIMONY IN OPPOSITION TO PORTIONS OF RES 16 OF THE CALIFORNIA PERFORMANCE REVIEW THAT RECOMMEND REPEAL OF SECTION 12811.5 OF THE FOOD & AGRICULTURAL CODE

submitted by:

BASF Corporation
Bayer CropScience LP
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Monsanto Company
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STATEMENT OF
INTERESTS & INTRODUCTION

THE LETTER OF AUTHORIZATION PROCESS (CPR RES 16)

The Recommendation to Repeal Food & Agricultural Code Section 12811.5 Should Be Rejected Because Letters of Authorization Encourage Development of Data to Support Pesticide Regulation, Promote Fair Competition, And Bring New Crop Protection Technology To The Agricultural Economy

This testimony is submitted to the California Performance Review Commission, by and on behalf of the following companies: BASF Corporation, Bayer CropScience LP, Dow AgroSciences LLC, E.I. du Pont de Nemours and Company, Monsanto Company and Syngenta Crop Protection, Inc. These companies respectfully oppose those portions of RES 16 in the Report of the California Performance Review which recommend the repeal of Section 12811.5 of the California Food & Agricultural Code.

The companies submitting this testimony are in the business of inventing, developing, manufacturing and distributing crop protection chemicals. These products are regulated in California as "pesticides" within the meaning of the Food & Agricultural Code, and thus must be "registered" with the State's Department of Pesticide Regulation ("DPR") before they may be manufactured, distributed, sold or used within the state. Collectively, the companies above hold approximately 635 such registrations. Each registration is supported by proprietary scientific research data to demonstrate that the product meets the State's statutory and regulatory criteria for registration. The companies submitted these data to the State under the protection of Section 12811.5 and other state statutes and regulations in effect since at least 1982, which ensure that their data will not be used by the State to support registrations for other companies without their written authorization. The data that DPR now holds on the companies' behalf, under the promise of protection under these laws, cost the companies hundreds of millions of dollars to produce and have a value to competitors that significantly exceeds their costs.

The proposed repeal of Section 12811.5 is intended to eliminate a process known as the "Letter of Authorization." This is the statutory and regulatory vehicle that allows the State's Department of Pesticide Regulation to use pesticide regulatory data submitted by one company to evaluate applications for similar products by other companies, provided that the owner of the data authorizes this use. The process facilitates registration for companies without registration data by allowing them to avoid tens of millions of dollars in testing costs, and streamlines the process for DPR by allowing the Department to rely on data submitted by the first registrant and thus avoid reviewing new data submitted by other manufacturers.

The companies above believe that Letter of Authorization process serves the State and its agricultural economy well and should not be eliminated. As noted, the Letter of Authorization process relieves DPR of significant burdens in reviewing duplicative data, in return for an insignificant investment of resources to perform the routine but necessary function of reviewing applications to ensure that they are accompanied by appropriate Letters of Authorization. In addition, the process maintains a level playing field for all pesticide manufacturers, and in so doing allocates the cost of participating in and supporting the California regulatory program evenly among pesticide registrants. The process also balances the benefits that the public obtains when innovator companies bring new crop protection products to the California market, at their own significant expense, with other benefits that are achieved by allowing imitator companies to bring proven products to the marketplace quickly and inexpensively.

For all of these reasons, the companies above believe Section 12811.5 should remain in effect. If the Commission recommends any changes to the Letter of Authorization process, they must be crafted carefully to achieve all of these goals. Any upset to this balance would not be in the best interests of environmental protection or California's agricultural economy.

EXECUTIVE SUMMARY

THE LETTER OF AUTHORIZATION PROCESS (CPR RES 16)

The Recommendation to Repeal Food & Agricultural Code Section 12811.5 Should Be Rejected Because Letters of Authorization Encourage Development of Data to Support Pesticide Regulation, Promote Fair Competition, And Bring New Crop Protection Technology To The Agricultural Economy

PESTICIDE REGULATION DEPENDS ON TESTING DATA DEVELOPED AND OWNED BY REGISTRANTS

California's Department of Pesticide Regulation (DPR) operates the most comprehensive pesticide regulatory program in the country and requires more health, safety, environmental and efficacy data to be submitted and reviewed than any other agency, even the US EPA. Section 12811.5 of the Food & Agricultural Code and various administrative regulations (Data Ownership Laws) establish a Letter of Authorization (LOA) process that is based on the same principles that apply under federal laws for submitting data to the US EPA — to effectively encourage companies to develop and submit this extraordinarily expensive intellectual property, agencies must accept the responsibility to protect its value and must spread this cost of developing and submitting data among the registrants whose products the data support. California's Data Ownership Laws are necessary because federal laws do not address the submission of data to states.

LETTERS OF AUTHORIZATION STREAMLINE THE REGISTRATION PROCESS AND SAVE AGENCY RESOURCES BY ALLOWING APPLICANTS TO OBTAIN STATE REGISTRATIONS WITHOUT DUPLICATIVE DATA

The LOA process was developed in 1982 to allow applicants without certain data to satisfy data requirements imposed under the California Environmental Quality Act (CEQA) and other State laws by obtaining authorization from inventor companies to use the studies they developed and submitted at their expense and that DPR already reviewed. An applicant still may conduct its own studies for DPR's review if it cannot obtain or does not desire the LOA, but this is rare. By allowing an applicant to avoid the massive costs of duplicating data, the LOA allows DPR to avoid reviewing duplicative studies and saves agency resources.

THE LETTER OF AUTHORIZATION PROCESS BRINGS NEW CROP PROTECTION TECHNOLOGY TO CALIFORNIA'S AGRICULTURAL ECONOMY AND PROMOTES FAIR COMPETITION

The Data Ownership Laws promote the introduction of newer, safer and more effective technology to control weeds, insects, and other pests to support California's agricultural economy by preserving an economic incentive for inventor companies to develop data and shoulder additional California registration burdens. The LOA process facilitates fair competition on a level playing field between inventor companies and imitator companies by requiring imitator companies to negotiate or pay for the LOA in return for using the data.

THE RECOMMENDATION TO REPEAL SECTION 12811.5 IS BASED ON FALSE PREMISES

The savings that DPR would realize from repealing the Data Ownership Laws, if any, are not legitimate and are vastly overstated. The supposed savings would be the asserted "costs" of screening applications for LOAs and tracking data, essentially clerical functions, which are miniscule compared to savings and efficiencies that LOAs achieve. Eliminating data owners' property rights to save these costs would violate the federal and State Constitutions and subject the State to liability for hundreds of millions of dollars. The LOA process does not duplicate the federal process, which does not compensate data owners for state use of their data.

THE ONLY GENUINE PROBLEMS WITH LETTERS OF AUTHORIZATION AROSE FROM DPR'S RECENT FAILURE TO OBSERVE THE DATA OWNERSHIP LAWS AND HAVE BEEN CORRECTED

LOAs have served the State and its farm economy well for over twenty years. The supposed inefficiencies of the LOA process were asserted only when DPR was sued by data owners for failing to observe the Data Ownership Laws. The ruling in that State suit and a second suit in federal court confirmed the validity of these Laws and should help DPR to simplify procedures for implementing them, if necessary.

OTHER RECOMMENDATIONS WOULD BE MORE EFFECTIVE TO ELIMINATE REDUNDANCIES AND SAVE COSTS

Associations representing pesticide manufacturers and the agricultural community have made other recommendations that would eliminate truly redundant and expensive DPR processes, *e.g.*, unnecessary reviews of some of the data previously reviewed by the US EPA. If implemented, these recommendations would result in significant savings and efficiencies for DPR, registrants, and the agricultural community. DPR could work with registrants to simplify the LOA process further, if that is necessary, without ignoring data owners' rights.

FULL TEXT

Of

Testimony In Opposition To

Portions Of RES 16 Of

The California Performance Review

That Recommend Repeal Of Section 12811.5

Of The Food & Agricultural Code

THE LETTER OF AUTHORIZATION PROCESS (CPR RES 16)

The Recommendation to Repeal Food & Agricultural Code Section 12811.5 Should Be Rejected Because Letters of Authorization Encourage Development of Data to Support Pesticide Regulation, Promote Fair Competition, And Bring New Crop Protection Technology To The Agricultural Economy

PESTICIDE REGULATION DEPENDS ON TESTING DATA DEVELOPED AND OWNED BY REGISTRANTS

The Department of Pesticide Regulation ("DPR") operates the most comprehensive pesticide regulatory program in the world. In doing so, DPR requires more health, safety, environmental and efficacy data to be submitted and reviewed than any other agency, even the US Environmental Protection Agency ("US EPA"). DPR evaluates each application for a pesticide registration to make its own determination whether the product will cause significant adverse impacts on the environment. *See* Regulating Pesticides; The California Story, Chapter 5, pp. 35 - 39, available at www.cdpr.ca.gov. These requirements are imposed by a number of state laws, including the California Environmental Quality Act ("CEQA") and provisions of the Food & Agricultural Code.

In order for DPR to make the regulatory determinations required under these laws, the Department must have access to scientific testing data. DPR regulations therefore require pesticide manufacturers to submit to DPR all of the data required by US EPA that support their federal registrations under the federal pesticide law known as the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). DPR regulations also require the submission of additional studies and reports, beyond the "federal data" referred to above. *See* 3 Cal. Code Regs., § 6170(a) ("Each application for registration of a pesticide product [shall be accompanied by] the data required to be submitted by sections 6159, 6170, 6172, 6176-6179, 6180(a), 6181-6192, and 6200 when applicable to support registration of the product. All data submitted to the U.S. EPA in support of federal registration of the product shall be submitted and all studies shall be submitted in full.")[1]

The data that DPR requires manufacturers to submit include studies to evaluate (a) acute health effects such as oral, dermal and inhalation toxicity, among others; (b) chronic health effects such as carcinogenicity, mutagenicity and fetal toxicity, among others: (c) potential for environmental damage; (d) toxicity to aquatic biota or wildlife; (e) methods of medical management of poisoning or other injuries; (f) analytical methods; (g) availability of alternatives; and (h) efficacy. *See* 3 Cal. Code Regs. § 6158. In addition to the "federal data" that address these matters, DPR regulations impose California-specific requirements to address factors such as safety related to exposure; mixer, loader and applicator exposure; foliar residue and field reentry; indoor exposure; residues; hazards to bees; and the presence of volatile compounds. *See* 3 Cal. Code Regs., Article 3, Supplemental Data Requirements.

After registrations are granted, DPR can, and frequently does, require manufacturers to develop and submit further expensive studies to support a process called "re-evaluation." *See* 3 Cal. Code Regs. § 6220 ("Reevaluation"), and § 6222 ("Reevaluation Data Requirements").

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[1] The regulation quoted above presently reads slightly differently in certain published versions of the California Code of Regulations. DPR purported to amend this regulation on July 5, 2002, to read as follows: "All data submitted to the [US] EPA ***by the applicant*** in support of federal registration shall be submitted, and all studies shall be submitted in full." (Emphasis added). The validity of the purported amendment currently is subject to litigation in two cases pending before the Second District of the California Court of Appeal, in part because DPR promulgated the amendment without opportunity for notice and comment in violation of its own regulations and the Administrative Procedure Act.. Regardless of the validity of this amendment, however, the point remains that DPR reviews all of the data submitted to US EPA in support of federal registration, and requires them to be submitted to DPR.

In addition, California registrants also are requested and often required to conduct further studies for use by DPR and other state agencies in order to allow those agencies to conduct additional evaluations and thus to maintain their California registrations in effect, and to commit additional extensive resources for product stewardship. Within the past few years, for example, manufacturers of certain pesticides have been required to conduct extensive air and monitoring studies and submit them to agencies other than DPR, or to satisfy DPR's concerns about compliance with requirements other than those for registration. The data owner for pesticides containing one active ingredient recently was required, by itself, to develop and submit air monitoring data at a cost of several million dollars to demonstrate for DPR that the use of these products did not raise air quality concerns.

The data described above typically cost tens of millions of dollars to produce. This is well-recognized and equally well-documented. For those who do not work regularly in this field, one of the most readily available sources of documentation is the opinion by the Supreme Court of the United States in the case of *Ruckelshaus, Administrator, United States Environmental Protection Agency v. Monsanto Company*, 467 U.S. 986 (1984) (hereinafter, "*Ruckelshaus v. Monsanto*"). The Supreme Court recognized in that case that "Monsanto had incurred costs in excess of $23.6 million in developing the health, safety and environmental data" that the company submitted to US EPA to obtain registrations for a pesticide pursuant to FIFRA. The cost of producing federal testing data and other studies required by DPR has only increased since that time. Informal industry surveys indicate that the cost of satisfying requirements to obtain federal registrations under FIFRA alone presently may exceed $50 million. Under the regulations discussed above, all of these data, and other additional studies, must be submitted to and reviewed by DPR.

Pesticide registration data also are extremely time-consuming to produce. It frequently takes from five to seven years to conduct the necessary studies, analyze resultant data, and then produce and submit the reports necessary to obtain regulatory approval for an agricultural pesticide. This significantly erodes the value of a patent on any product.

Independently of the expense and time required to develop them, pesticide registration data are extremely valuable to pesticide manufacturers. Most registration data are considered trade secrets under state and federal laws that define such property, in part because of their value to pesticide manufacturers in the development of new products.

For these reasons, pesticide registration data remain the property of the companies that develop them, even after the data are submitted to federal and state agencies for regulatory review. In effect, the agencies hold registration data in trust for their owners. The agencies are permitted to use the data on behalf of the public to evaluate pesticides, and in some cases may release the data to members of the public. The agencies may not release the data to other manufacturers, however, and may not use them to benefit other manufacturers except as certain statutes specifically allow.

At the federal level, FIFRA protects the status of pesticide registration data as trade secrets, and allows the data to be used for the benefit of competitors only under a complicated "use/compensation" scheme. The scheme prohibits US EPA from using a company's data to support the registrations of any competitors under any circumstances for a period consisting of the first ten years after the data are submitted to the Agency (unless, of course, the owner of the studies gives its permission). The scheme then prohibits US EPA from using the data to support a competitor's registration for the following five years, unless the competitor makes a written offer to pay compensation for their use and submits to binding arbitration if the owner of the data and the competitor cannot agree as to the "amount and terms" of compensation. *See* FIFRA § 3(c)(1)(F). Then, after both of those periods expire (a total of fifteen years), the Agency may use the data in the absence of compensation to their owner to support *federal* registrations for competitors. The Agency still may not release the data to competitors, or provide them to state or foreign governments to support their registration requirements.

At the state level, data submitted to DPR similarly retain their status as trade secrets under the California Uniform Trade Secrets Act, in addition to more specific trade secrecy provisions under the Food & Agricultural Code and California's Public Records Act which, in a fashion similar to federal laws, also allow for the release of data to interested members of the public but not to competitor manufacturers. Finally, under the State's "Data Ownership Laws, DPR is prohibited from using the data to support registrations of a competitor unless the owner of the data provides a Letter of Authorization permitting DPR to do so. The Data Ownership Laws, their history and their purpose are discussed in further detail below.

LETTERS OF AUTHORIZATION STREAMLINE THE CALIFORNIA REGISTRATION PROCESS AND SAVE AGENCY RESOURCES BY ALLOWING APPLICANTS TO OBTAIN STATE REGISTRATIONS WITHOUT SUBMITTING DUPLICATIVE DATA

The Letter Of Authorization process was developed in 1982 to allow applicants without certain data to satisfy data requirements imposed under CEQA and other state laws by obtaining authorization from companies that invent pesticides and incur the multi-million dollar expense of developing registration data. DPR's predecessor, the California Department of Food & Agriculture ("CDFA"), established the Letter of Authorization process by regulation in 1982. That regulation presently is found at 3 Cal. Code Regs. § 6170(c).

The Legislature reinforced this provision in 1996 by enacting Section 12811.5 of the Food & Agricultural Code. The bill that resulted in Section 12811.5 was sponsored by DPR, passed unanimously by the Legislature, and signed by Governor Wilson. The officials running DPR in 1996 indicated that the statute was necessary to "plug a loophole" in the process established under 3 Cal. Code Regs. § 6170(c). According to the Department, applicants for registration were able to obtain studies from DPR under the Public Records Act and submit them as if they owned them, without obtaining a Letter of Authorization from the true owner. The bill that became Section 12811.5 thus was introduced to "prevent unauthorized and uncompensated use of another person's scientific data . . . ." DPR Analysis of Senate Bill 802, p. 2. The intent of the bill was to prevent some registrants from getting a "free ride" through the regulatory process, at the expense of companies that support the process by producing the data that the State needs and requires.

THE LETTER OF AUTHORIZATION PROCESS BRINGS NEW CROP PROTECTION TECHNOLOGY TO CALIFORNIA'S AGRICULTURAL ECONOMY AND PROMOTES FAIR COMPETITION

These Data Ownership Laws have promoted the introduction of newer, safer and more effective crop protection chemicals that support California's agricultural economy and have maintained a level playing field for all pesticide manufacturers. The Letter of Authorization process has allowed companies without data to avoid most California registration costs, provided only that they reach a mutually satisfactory commercial arrangement, such as compensation, with the company that incurred the costs. This facilitates competition among pesticide manufacturers, yet preserves the economic incentive for innovator companies to bear the costs of developing and submitting the data that support DPR's Pesticide Regulatory Program and other costs associated with California's regulatory process.

The Letter of Authorization also has facilitated the registration process for the State by allowing DPR and its predecessor agency to avoid reviewing multiple sets of duplicative data for similar pesticides. The process does not require DPR to review additional data. Rather, it is a short-cut to registration for an applicant and for DPR alike. If an applicant presents a Letter of Authorization for data previously submitted by another company that address California data requirements, then DPR need not review those data again.

The Letter of Authorization process is similar, though not identical, to the federal "use/compensation" process under FIFRA, referred to above. FIFRA, of course, does not require states to accept federal registration decisions, but rather leaves states with the authority to regulate pesticides themselves. This includes the authority for states such as California to require applicants for state registration

to submit to state agencies the data previously submitted to US EPA for independent state review, and to establish supplementary state data requirements, if they choose. Companies that submit their data to US EPA are under no obligation to allow competitors to use the data to obtain state registrations, and would not be entitled to compensation under FIFRA if they chose to do so. Nor do they receive compensation under FIFRA for other data they submit to states to obtain state registrations, or for the other costs they may incur to obtain or maintain state registrations. Inasmuch as DPR, in a way that sets it apart from any other state pesticide regulatory agency, has exercised its authority to require the re-submission of "federal" data and to impose significant additional state requirements, the Letter of Authorization process serves the same necessary purpose in California that the "use/compensation" process serves at the federal level under FIFRA.

The Letter of Authorization process thus fills a void that otherwise would exist under the California regulatory scheme. It serves simultaneously as (1) the vehicle for allowing registrants without data of their own to obtain registrations; (2) as the means by which DPR can avoid reviewing duplicative studies; (3) the mechanism through which data owners can obtain compensation for the use of their studies by others; and, therefore, (4) a system through which the costs of supplying the data that are necessary to support the State's Pesticide Regulatory Program can be allocated fairly among all of the companies that obtain state registrations.

THE ONLY GENUINE PROBLEMS WITH LETTERS OF AUTHORIZATION AROSE FROM DPR'S RECENT FAILURE TO OBSERVE THE DATA OWNERSHIP LAWS AND HAVE BEEN CORRECTED

The Letter of Authorization process has worked well for over twenty years. The only complaints came from companies demanding the "free ride" that the Legislature had decided was inappropriate. A few years ago, however, DPR issued pesticide registrations to two pesticide manufacturers that did not own all of the data necessary to support registrations for their products and failed to obtain Letters of Authorization. This triggered two lawsuits, summarized below, in which state and federal courts affirmed the validity of the Data Ownership Laws. Those suits are concluded at the trial level. Appeals are now pending that should resolve any remaining issues.

State Court Lawsuits: Two data owners whose data were used without their permission filed suits in 2001 and 2003, requesting a state court to order DPR to enforce the Data Ownership Laws. DPR defended these suits by arguing that the Department has complete discretion to determine what data are required to support each registration, on a case-by-case basis. DPR argued that it may use this discretion to determine what data its regulations "require," and to "waive" data requirements when it chooses. Therefore, DPR argued, it did not "use" or "consider" the data in its files when it issued registrations to companies without data. Rather, the Department simply determined that the data that one company had already submitted were no longer "required" for other companies. DPR appropriately conceded, however, that the Department could not lawfully issue a registration to any applicant for a pesticide unless all of the data requirements for that product had not previously been satisfied. The state court reasoned, correctly, that DPR's proffered interpretation of the data requirements would be in conflict with DPR's obligations under the Data Ownership Laws, and thus ruled that DPR violates Section 12811.5 when it fails to impose the same data requirements for one company that were imposed on another, in the absence of a Letter of Authorization.

Notwithstanding the state Court's ruling, DPR allowed the registrations at issue in the suits to be renewed, and then issued more registrations to other companies without data that did not obtain Letters of Authorization. According to documents submitted to the Court, DPR was proceeding with "business as usual" because, in its view, the Court's order was "vague." As a result, the data owners requested the state court to issue an injunction. DPR then promised on the record to comply with the Court's ruling, through its attorney from the State Department of Justice. Thus, DPR now has acknowledged the effect of the Court's order, and has promised to the Court that it will comply with the ruling unless it is modified by the Court of

Appeal. To the extent that any issues remain regarding the proper implementation of these laws, those issues soon will be resolved.

Federal Court Lawsuit: While the State Court Lawsuits were pending, a trade association consisting of pesticide manufacturers that do not invent their own products or develop data to support registrations filed another suit in a federal court, arguing that the Data Ownership Laws are pre-empted by the "use/compensation" provisions of FIFRA. The innovator companies that are submitting this testimony intervened to defend the constitutionality of the State's laws, and the federal court ruled that the Data Ownership Laws are not pre-empted. Following the ruling, the trade association moved for re-consideration. The federal court sustained its previous ruling, and thus held a second time that the State Data Ownership Laws are not pre-empted. Although the trade association has appealed these decisions, the two rulings of the trial court appear to be dispositive.

THE RECOMMENDATION TO REPEAL SECTION 12811.5 IS BASED ON FALSE PREMISES

RES 16 of the California Performance Review includes a recommendation to repeal the Data Ownership Laws that establish the Letter of Authorization process. It is clear from the text of the Report that RES 16 is based on recommendations proposed by the Department. It is equally clear that DPR's recommendations were made in the context of the lawsuits described above. The justifications for the recommendation appeared to be a product of advocacy then, and are even less valid now that the courts have ruled. If there was any confusion about the meaning or validity of these laws, that has been resolved.

The savings that DPR would realize from repealing the Data Ownership Laws, if any, are not legitimate and are vastly overstated. The supposed savings would be the asserted "costs" of screening applications for Letters of Authorization and tracking data, essentially clerical functions, which are miniscule compared to savings and efficiencies that Letter of Authorization achieve. Eliminating data owners' property rights to save these costs would violate the federal and state Constitutions and subject the State to liability for hundreds of millions of dollars. The Letters of Authorization process does not duplicate the federal process, which does not compensate data owners for state use of their data.

The Department clearly can administer the registration process without ignoring property rights of data owners, and it is not necessary for the Governor or the Legislature to attempt to strip companies that submit data of their property rights. If there is any legitimate need for further efficiencies in the Letter of Authorization process, then DPR can find a way to achieve them without simply ignoring the rights of the owners of property in which it has been entrusted.

The CPR Recommendation. The CPR recommends that the "Governor should work with the Legislature to repeal Section 12811.5 of the Food and Agriculture Code, which prohibits [DPR] from considering data in support of a registration unless the registrant has received written permission from the original data submitter."

In support of this recommendation, the CPR recites that

> "[r]epealing this section would allow DPR to rely upon any data on file, regardless of data ownership, to support the registration of a new pesticide product or an amendment to a currently registered pesticide product. Eliminating this additional authorization step would save DPR staff time and resources without affecting its core mission of protecting public health and the environment. It would also accelerate DPR's decision-making process on registration requests. DPR should redirect staff resources toward completing pesticide health and safety reviews and other critical tasks necessary to register pesticides in the state."

The Letter Of Authorization Process Relieves DPR And Applicants For Registration Of Significant Burdens, In Return For A Minimal Investment Of Resources. As stated above, the Letter of Authorization process is a short-cut to registration for companies that do not have the means or inclination to produce the expensive data that are necessary to support a registration. It allows applicants for generic registrations to support their applications without duplicating data, provided only that they are willing to support the costs of the data by compensating the data owner for the cost of producing them.

The Letter of Authorization process simultaneously relieves DPR of the burden to review duplicative studies that otherwise would need to be submitted to support each application, provided that the generic applicant obtains and submits a letter of authorization regarding the required data. This burden falls on the generic registrant, rather than on DPR.

The burden on DPR staff and resources to manage the data submitted to the Department is slight, if any, especially compared to the burden that would be incurred if each applicant for registration were required to generate its own duplicative data and DPR were required to review each applicant's data. The burden of which DPR complains in statements referred to in the CPR Report is essentially a clerical function, which relates only to the management of the data it holds on behalf of data owners and to reviewing applications for Letters of Authorization.

Specifically, DPR has asserted that fifty percent of the time of its registration staff is "spent dealing with issues related to letters of authorization *and efficacy data reviews*" (emphasis added). This confuses two separate issues, and does not justify stripping data owners of their property rights. While DPR may expend significant resources reviewing efficacy data (which is unnecessary in many cases), it is hardly credible to assert that a significant portion of DPR's registration staff is consumed with managing Letters Of Authorization. As noted above, keeping track of Letters of Authorization and keeping files that safeguard the data with which DPR is entrusted are essentially clerical functions. Collectively, these tasks are a prerequisite to an effective data management system. If DPR truly is spending half of its registration resources managing rather than reviewing data, which we doubt, then it would be more appropriate and far more prudent to address this issue by working with data owners and applicants for registration, rather than simply ignoring the property rights of data owners.

The Recommendation Ignores The Rights Of Data Owners In Their Intellectual Property. As noted above, the Letter of Authorization process worked smoothly and without significant complaints or controversy for nearly twenty years, until DPR issued registrations to companies that ignored its requirements. Objective analysis, produced on the basis of evidence in the Federal Court Lawsuit, demonstrated that the Letter of Authorization process facilitated over 13,000 registrations in the years from 1994 - 2003, thus eliminating the need for the submission of and review of countless environmental, health, safety and efficacy studies.

Any problems in the administration of this system can arise only in the relatively few cases where a registrant chooses to reproduce data, rather than pay or negotiate a commercial arrangement with a data owner for the costs of relying on or "citing to" data that were previously submitted. This is an insignificant percentage of the applications submitted. It is not legitimate for DPR to propose to solve this relatively minor problem simply by using the data that belong to another company without its authorization or, to quote the CPR Report, "regardless of data ownership."

The Recommendation Raises Constitutional Issues. Under the Takings Clause of the United States and California Constitutions, the State cannot take intellectual property rights away from the owner of data, after the owner submits them to the State with an "investment-backed expectation" created by statute, regulation or agency practice that the data would be used exclusively to support the owner's registrations. The Supreme Court addressed this issue under nearly identical circumstances in ***Ruckelshaus v. Monsanto,*** discussed above. Under the Equal Protection Clause, moreover, the State must treat all similarly situated

applicants for registration equally. It cannot discriminate between the first applicant and subsequent applicants for the same product by failing to apply the same requirements for registration to each.

Any changes to Section 12811.5 or the outright elimination of the Data Ownership Laws would raise similar constitutional issues. Legislative action that results in an unconstitutional "taking" of property prohibited under the Fifth Amendment would subject the State to hundreds of millions of dollars of liability, for no real benefit except to allow a few producers who do not support the costs of California's regulatory program to obtain a "free ride" through the regulatory process.

The Recommendation Would Reduce Incentives For Innovator Companies To Bring New Crop Protection Technologies To The California Agricultural Market. The number of innovator companies in the crop protection chemical industry has been reduced markedly in recent years, leaving fewer companies to bear an increasing proportion of the costs of California's data requirements. It is significant that these few remaining data developers do not receive compensation under federal law for the use of their data by state agencies, if a state agency such as California requires them. Indeed, the compensation that innovator companies do receive under the FIFRA "use/compensation" system for the use of their data at the federal level typically is diminished because California imposes its own registration requirements and US EPA's use of data to issue a federal registration therefore does not in itself result in or guarantee a California registration. Without a mechanism like the Letter of Authorization process, data developers would receive no compensation at all for the use of their data by competitors in California.

A further consideration that is particularly important is the need for data specifically to satisfy California's regulatory purposes, including data that are required for "re-evaluation" or to support determinations by other California agencies, such as water or air authorities that operate independently of DPR, or to satisfy DPR that the use of a product does not raise such water or air concerns. As noted above, it is not uncommon for data owners to incur costs in the millions of dollars to satisfy such concerns after a registration is issued, which benefit DPR, the agricultural community and the environment. One of the benefits of the Letter of Authorization Process and the "level-playing field" that it creates is to spread the costs of California's pesticide regulatory program across all of the registrants who participate in the California market, and not just a few. If the Letter of Authorization process is eliminated, the "playing field" will become tilted to favor manufacturers of imitator products that do not develop data to obtain registrations and keep them in effect. Innovator companies, moreover, will have less reason to bear the additional costs of obtaining registrations in California for the newer, safer and more effective crop protection products that benefit the agricultural and environmental communities.

OTHER RECOMMENDATIONS WOULD BE MORE EFFECTIVE TO ELIMINATE REDUNDANCIES AND SAVE COSTS

Associations representing pesticide manufacturers and the agricultural community have made other recommendations that would eliminate truly redundant and expensive DPR processes, *e.g.*, unnecessary reviews of some of the data previously reviewed by US EPA. A copy of a proposal put forward by the California Cotton Growers Association, California Farm Bureau Federation, California Plant Health Association (now referred to as the Western Plant Health Association), the California Seed Association and the Consumer Specialty Products Association, entitled "Program Reforms for the California Department of Pesticide Regulation" ("Program Reforms") is attached to this testimony.

The Program Reforms recommended by these important associations of agricultural interests address the real crux of the high costs, delays, and inefficiencies imposed by California's Pesticide Regulatory Program. Many of DPR's procedures are redundant of procedures undertaken by federal agencies. Indeed, virtually all of the data submitted to and reviewed by DPR have been submitted to and reviewed by US EPA as a prerequisite to federal registration. In light of requirements imposed by CEQA, it may continue to be necessary for registrants to submit all of the data that support their federal registrations. Nevertheless, the

proposals put forward in the Program Reforms, if implemented, would allow DPR to rely on the US EPA reviews of these data in many cases, and thus would eliminate many redundancies. Importantly, they would not diminish protection of human health, safety or the environment. Eliminating the need for some of these redundant reviews, however, undoubtedly would result in significant savings and efficiencies for DPR, for registrants, and for the agricultural community.

ALTERNATIVES TO ELIMINATING THE LETTER OF AUTHORIZATION PROCESS

Innovator companies believe that the Data Ownership Laws should not be changed. These laws establish the right economic incentives to ensure that new technology continue to be available to the California grower community, and strike the proper balance with other important environmental and economic concerns. These laws need to be enforced, not repealed.

If the present Letter of Authorization process were to be changed, notwithstanding all of the reasons for retaining the process in its present form, then any changes would have to be considered carefully and comprehensively, in order to ensure that all the benefits of the process continue to be achieved and the property rights of data owners are observed. Any discussions of proposals to change the process should include the following points.

First, any amendments must continue to provide an incentive to innovator companies to submit data to the State and to develop the additional data and incur the additional costs to obtain and maintain California registrations. These incentives must address specifically the requirements to develop data for re-evaluation and to address concerns after registrations are issued, including concerns of other regulatory agencies. Without these incentives, innovator companies will be less likely to bear the additional costs of introducing new technologies to the California marketplace and keeping them registered in California.

Second, any amendments must be prospective only. It would be unfair and unconstitutional to use one company's data to support another company's product after the owner submitted its studies to the State, with statutory promises that the data would be protected. The United States Supreme Court already has ruled that retroactive changes result in an unconstitutional "taking" of property.

Finally, any amendments should encourage fair competition. It is not fair to require innovator companies alone to bear the costs of producing the data that the State needs to protect the environment and health, and to allow other manufacturers to have a "free-ride." It would not be fair to use their data without their consent after they submit data to the State. And it would not be fair to leave data owners without a legal mechanism to recover the value of their data, if the State should change the law to compel the use of their data on behalf of competitors without their permission.

ATTACHMENT

Program Reforms For

The California Department

Of Pesticide Regulations

PROGRAM REFORMS FOR THE CALIFORNIA DEPARTMENT OF PESTICIDE REGULATIONS

Submitted by:

California Cotton Growers Association
California Farm Bureau Federation
California Plant Health Association
California Seed Association
Consumer Specialty Products Association

Contents

March 26, 2004

The Honorable Arnold Schwarzenegger
Governor
State of California
State Capitol
Sacramento, California 95814

Dear Governor Schwarzenegger:

This report is being submitted by a coalition of agricultural and consumer product organizations in California. We work on an ongoing basis with a variety of agencies to craft public policies at both the legislative and regulatory level to ensure environmental protection while maintaining reasonable costs for users of our products. While we represent various interests, we share similar concerns with California's other businesses about the increasing burdens placed on the state's business community in the form of excessive fees and taxes, onerous environmental rules and regulations, and additional mandates that result in questionable environmental benefits.

Of particular concern is the Department of Pesticide Regulation (DPR). We believe that a strong department is a benefit to everyone in California. DPR is currently challenged by budget shortfall, and is looking to fill that shortfall through increased fees on industry. Rather than moving to higher fees, DPR should implement reforms to eliminate program redundancies that increase program costs, and decrease the timeliness of pesticide registrations. This is an opportunity to truly review DPR's current programs, and implement reforms that will allow DPR to better serve Californian's.

The following document is a series of proposals to improve DPR's ability to serve California through reforms in regulation, statute and through administrative initiatives. We believe these changes will assist DPR in improving its programs and departments.

Environmental protection and economic growth are not mutually exclusive goals and we thank you in advance for considering our views.

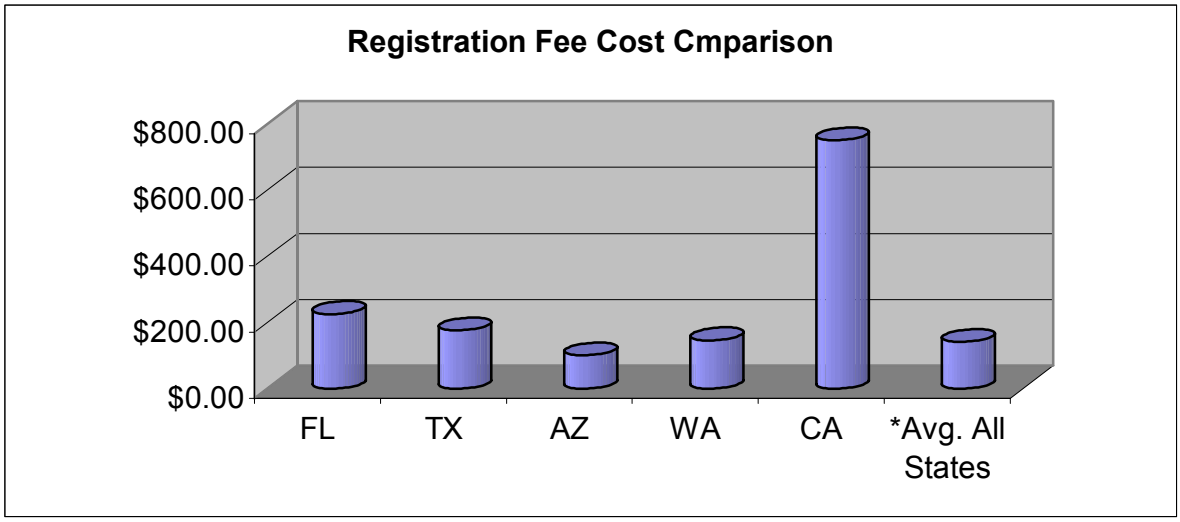
DPR Program Cost Comparison

This section illustrates cost differences between California and other agricultural states. It demonstrates the tremendous disadvantage California growers and consumers are put at by being at risk of not having the same products available as other states, and the dramatically higher regulatory costs that they must absorb.

The following are annual registration fees paid per product/brand. Also included is the *average* number of products registered in each state and the total cost to agriculture in registration fees per state.

	Annual Fee	# of Products		Total Costs
Florida:	$225 per brand	(13,900)	=	$3,127,500
Texas:	$175 per product	(15,000)	=	$2,625,000
Arizona:	$100 per product	(9,500)	=	$ 950,000
Washington:	$145 per product	(10,500)	=	$1,522,500
California:	$750 per product	(12,000)	=	$9,000,000

Average: $140.00 per product (*The average registration fee for all states except California)

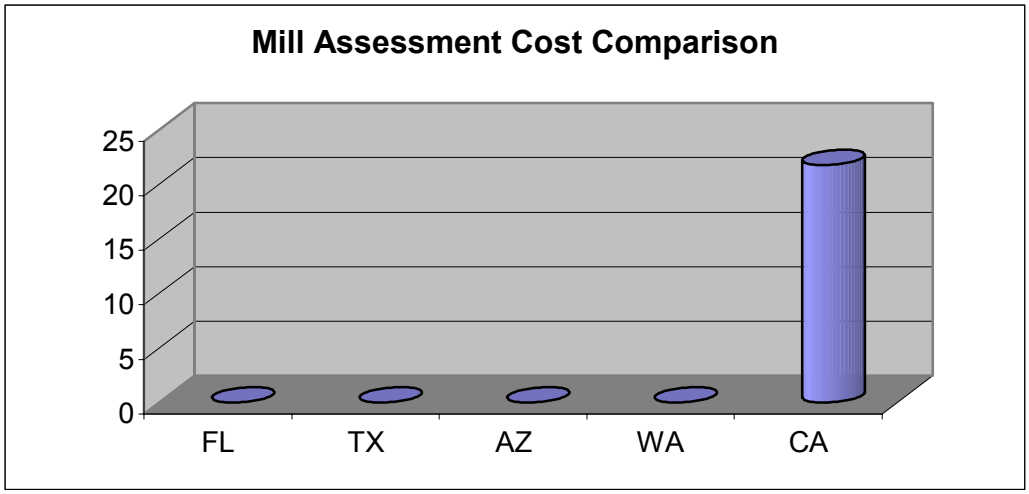


For agriculture, costs are set locally and prices are set globally. California growers compete with growers from other states with lower costs, and with growers from other countries who face little regulation.

California growers and manufacturers pay an assessment based on dollar sales for each product sold in California. This assessment funds DPR programs that serve both agriculture and the general public.

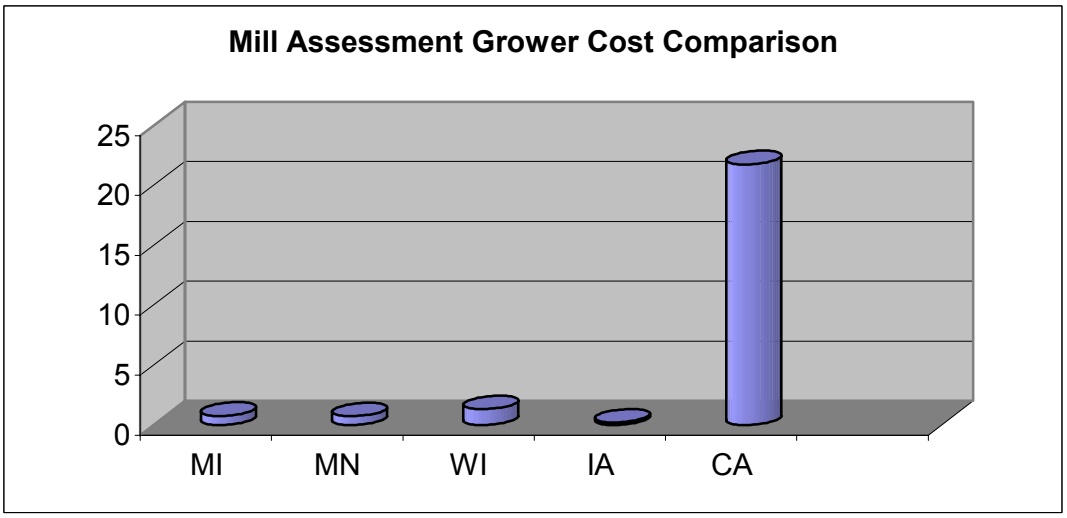
The following chart demonstrates the dramatic cost difference to California growers and manufacturers compared to other select states.

Florida:	.00 mills
Texas:	.00 mills
Arizona:	.00 mills
Washington:	.00 mills
California:	21.75 mills



Four states have implemented mill assessment programs. The following chart demonstrates the cost difference between California and those states.

Michigan:	.75 mills
Minnesota:	.7 mills
Wisconsin:	1.3 mills
Iowa:	.2 mills
California:	21.75 mills



Historical Background on Pesticide Regulation

California's complicated registration process is based on inadequacies in the scope and quality of scientific evaluations of pesticides that the public, over the course of several decades, felt needed to be addressed in California. Federal statutes and programs have been implemented more recently to fill those gaps on a federal level. California's Department of Pesticide Regulation (DPR) staff provided leadership in the development of these scientific standards and should be recognized for their efforts in contributing to the nation's current pesticide regulatory programs. However, as USEPA has moved to fill these data gaps and programs on a federal basis, and require the production and evaluation of scientific studies that provide full environmental and health protection to the public, California has failed to adjust its own regulations to recognize these new federal activities.

The following is a brief description of the development and timeline of "modern" pesticidal regulations, from California and USEPA.

1970'S: CA CONCERNS WITH USEPA'S PESTICIDE PROGRAM

- **CA Concern**: USEPA did not adequately address **worker exposure issues** for California's specialty crops.
    - **CA Response**: Establish and expand **worker health and safety programs** to independently ensure worker and user protection under California's unique conditions.

1980'S: CA CONCERNS WITH USEPA'S PESTICIDE PROGRAM

- **CA Concern**: Older active ingredients **not adequately evaluated** by USEPA.
    - **CA Response**: CA **expanded data requirements** to include all data required by USEPA.
    - **CA Response**: CA **required full studies**, not just summaries of studies.
    - **CA Response**: CA **initiated thorough evaluation** of all studies, regardless of whether USEPA evaluation had been performed previously
- **CA Concern**: USEPA was **not consistently evaluating health effects data** on pesticides.
    - **CA Response**: **SB-950**. Birth Defects Prevention Act required submission of "mandatory health effects studies" for all active

ingredients. Required that studies meet USEPA's acceptability criteria.

- **CA Concern**: USEPA was **not adequately evaluating for potential groundwater contamination**.
    - **CA Response**: **AB-2021.** Pesticide Contamination Prevention Act required submission of certain studies relevant to the potential to contaminate groundwater. Acceptance of studies based on USEPA's criteria.

EARLY 1990'S: USEPA PESTICIDE PROGRAM CHANGES:

- **Re-Registration Program Establish**ed: Federal Insecticide, Fungicide, & Rodenticide Act (FIFRA) amendments mandated that USEPA thoroughly reevaluate all existing pesticides and bring all data up to modern standards.

- **Antimicrobial Division Established:** USEPA created a new division to focus their efforts on antimicrobial products, similar in structure and purpose to their biopesticide products division.

- **Health Effects Data Review Standards Established:** USEPA established consistent evaluation standards for health effects studies and mandated evaluations for all products of concern.

- **Groundwater Data Evaluation Program Established:** USEPA adopted formal policy for evaluating potential to contaminate groundwater, coupled with policies restricting uses for ingredients of concern.

DPR: Program Reform Overview

There are four major areas of reforms that would improve the efficiency and timeliness of the registration process. They include the Elimination of Redundancy, Increasing Timeliness, DPR Primacy on Pesticide Issues, and Protecting California's Unique Pest Protection Needs.

ELIMINATE REDUNDANCY

Through the 1980's, in response to concerns about the inadequacies of the federal pesticide registration processes, California adopted numerous statutes, regulations, and policies that require the state to "double-check" most federal decisions on pesticides. The result is a pesticide program in California that, unlike any other state, is largely redundant with the processes and decisions at the federal level regarding the safety, use, and registration of pesticides. A series of amendments to the FIFRA initiated in the late 1980's significantly changed the thoroughness and integrity of the federal processes, rendering many of the California processes obsolete and redundant.

INCREASE TIMELINESS

The complexity of California's pesticide regulatory processes typically result in delays of new and improved products entering the state. This results in California production agriculture being without tools that are available to both neighboring states and other competitive growing regions within and outside the United States. New and improved products designed to meet the ever-changing consumer needs are delayed entry into the state, limiting consumer choice and hampering national distribution.

ENSURE DPR PRIMACY ON PESTICIDE ISSUES

There are several regulatory agencies with varying levels of oversight of pesticides. However, DPR, has the broad expertise required to thoroughly assess and manage pesticide issues. DPR's combination of scientific, regulatory, and enforcement specialization should be utilized by the state to streamline the handling of these issues into a single unit.

PROTECT UNIQUE PEST PROTECTION PROGRAMS

California has a unique and diverse agricultural environment with numerous pest control challenges that are specific to our state. FIFRA includes processes that are specifically designed to respond to these unique requirements; "Emergency" and "Special Local Need" registrations. California should evaluate and reform the processes by which these crucial registrations are evaluated and supported by the state.

Regulatory Reforms to DPR Programs

The following is an overview of regulatory reforms that will enhance the registration process.

ELIMINATE REDUNDANCY

A. Use USEPA Evaluations of Scientific Data

DPR should use the USEPA's scientific evaluations of studies, in lieu of their own, to eliminate duplicate scientific reviews. When these USEPA scientific evaluations are available, independent evaluations of these same studies by DPR staff should be performed only when specific issues or concerns regarding an application for registration are identified by DPR.

B. Eliminate Efficacy Data Reviews for Categories of Products

USEPA routinely evaluates scientific data supporting efficacy claims on products such as antimicrobial products with health claims, public health products, and termiticides. For other product categories, USEPA require that supporting data be available and subject to evaluation on an as-needed basis. DPR's redundant evaluation of products already evaluated by the USEPA should be eliminated (consistent with Food & Agriculture Code section 12837, approved by legislature in 1996) as should the evaluation of products when user groups do not request DPR's input (e.g. consumer products). For other product categories, the policies for performing efficacy evaluations should be evaluated by all impacted parties after various current legal clarifications have been finalized.

C. Eliminate Other Scientific Evaluations

DPR performs redundant evaluations of studies in several other categories including 1) residue chemistry data; 2) fish and wildlife data; 3) product chemistry data; and 4) acute toxicity data. The requirement for these data reviews could be eliminated with insignificant impact on either public health or the environment since the analogous evaluations of these same studies and the assessment of their impacts on environmental and health risks are being performed by the USEPA.

Summary. California should eliminate the requirement for submission and evaluation of all studies that are mandated by USEPA, unless, under a scientifically based finding by DPR, duplication is needed. Attached is a chart entitled "DPR AND USEPA PESTICIDE DATA REQUIREMENTS" with notations where studies are duplicated.

INCREASE TIMELINESS

DPR must adhere to existing 60 and 120 day regulatory mandates for their completion of decisions on applications for pesticide registration or face sanctions for failing to perform their functions as mandated (California Code of Regulations section 6151). In 1997 the legislature added Food and Agriculture Code section 12824, which required DPR to report on its progress towards compliance with timely registration requirements. DPR should provide this report, with customer input, so that the legislature and the administration can objectively evaluate DPR's performance. DPR should fully implement a tracking of the registration process so that users can identify their status and parties can identify delays in the process where improvements are necessary.

A. Expand Work-Share of Scientific Evaluations with USEPA

Currently, DPR and USEPA perform duplicative evaluations of most scientific studies. These programs have been very successful but, because these programs are largely duplicative, collectively they are not an efficient use of government resources.

DPR should aggressively pursue sub-contracting with USEPA to perform data reviews. The reviews would be conducted once, DPR would generate additional revenues in the process, and growers and other users of these products would have more immediate access to these tools. DPR has stated in the past that USEPA did not have funding for this purpose. Recent changes in federal law now allow USEPA to conduct evaluation on a fee-for-service basis. The Office of Pesticide Programs stated on February 4, 2004, that it would hire additional personnel as outside consultants for this role.

B. Adopt USEPA's Scientific Guidelines and Standards

When evaluations of applications for pesticide registration are performed by DPR, significant delays in the process can be caused by rejection of scientific studies by DPR that were accepted by USEPA, or use of policies by DPR that do not match those followed by USEPA. DPR should ensure that their standards, unless they are directly related to California's unique environmental and workplace settings, are consistent with those of the USEPA.

C. Streamline Registration Process

The current pesticide evaluation process is followed by a mandatory 30-day posting period. To expedite the registration process, DPR should incorporate this 30-day posting period into the evaluation process.

Statutory Reforms to DPR Programs

The following is an overview of statutory reforms that will improve the efficiency of the registration process. While they may be more challenging to achieve than regulatory reform, these changes would result in major efficiencies to DPR.

ELIMINATE REDUNDANCY

A. Evaluations Required by Statute (SB-950 and AB-2021)

Scientific evaluations specifically mandated in the 1980's (under Articles 14 and 15, Chapter 2, Division 7 of Food & Agriculture Code) have been subsequently performed by the USEPA as part of their routine regulatory process. California statutes should be amended to eliminate the mandatory requirements for these now largely redundant reviews, accepting USEPA's evaluations in place of DPR evaluations, where possible. The scientific risk assessment programs covering human health and the environment that are required under these 1980's laws should continue.

B. Eliminate OEHHA Evaluations of DPR Documents (SB-950)

The Birth Defects Prevention Act (SB-950) requires that the Office of Environmental Health Hazard Assessment (OEHHA) be consulted if certain health effects studies are being considered for waiver by DPR or when DPR produces a Risk Characterization Document under the Act. The University of California also peer reviews DPR's Risk Characterization Documents. The following redundant evaluations should be eliminated.

1. **OEHHA Consultation in Health Effects Study Requirements -** Mandatory redundant evaluations by two groups of state scientists regarding study requirement decisions is inefficient. These decisions should remain with the state's experts in pesticide health effects, DPR, and allow for consultation when these experts find that additional input is appropriate.

2. **OEHHA Peer Review of DPR's Risk Characterization Documents –** This review is particularly unnecessary, as DPR and the University of California are required to conduct a peer review process for DPR's Risk Characterization Documents. This adds a third independent assessment to the process and should be eliminated.

INCREASE TIMELINESS

A. Expand Concurrent Evaluations With USEPA

DPR has recently eliminated many of the previous policies that allowed DPR to concurrently evaluate applications with the USEPA. The result is delays of new pest control tools into California. The concurrent evaluation of 1) Reduced Risk Products, 2) Microbial and Biochemical Products, 3) New Active Ingredients, and 4) Substantial New Uses for Existing Products that are already registered by DPR should be reinstated and expanded, including the sharing of data evaluation burdens with the USEPA wherever possible.

While most of the areas covered under this category could be reinstated through an administrative initiative, where the product is a health related antimicrobial statutory change is required. As a result, we are listing these categories in both the statutory and administrative initiative sections.

Summary. As stated in the "Regulatory Reforms to DPR Programs" section, California should eliminate the requirement for submission and evaluation of all studies that are mandated by USEPA, unless, under a scientific finding by DPR, a duplicative evaluation is needed. Attached is a chart entitled "DPR AND USEPA PESTICIDE DATA REQUIREMENTS" with notations where studies are duplicated

Administrative Reforms to DPR Programs

The following are reforms that through Administrative initiatives including, executive orders, inter-agency reorganization, or "Memorandum's of Understanding" would improve the DPR registration process and increase the effectiveness of California's pesticide programs.

INCREASE TIMELINESS

A. Expand Concurrent Evaluations With USEPA

The concurrent evaluation of 1) Reduced Risk Products, 2) Microbial and Biochemical Products, 3) New Active Ingredients, and 4) Substantial New Uses for Existing Products, should be reinstated and expanded, including the sharing of data evaluation burdens with the USEPA wherever possible.

This process would require both administrative and statutory changes. Please see comments under "Increasing Timeliness" within "Statutory Reforms of DPR Programs" section.

ENSURE DPR PRIMACY ON PESTICIDE ISSUES

A. Ensure Lead Role in Air Quality Regulations

The Air Resource Board (ARB) has the statutory responsibility for meeting air quality standards but lacks needed technical expertise on agricultural and industrial use pesticides to implement standards as they apply to agricultural uses. DPR should have the lead role in developing and setting regulations that are achievable, with ARB having a consulting role to assure that their statutory mandates are met. For consumer products, ARB should continue with their primacy role.

B. Ensure Lead Role in Surface- and Ground-Water Quality Regulations

The State and Regional Water Board's and Department of Fish and Game staff lack the technical expertise on pesticides compared to DPR. DPR should be the lead agency in developing regulations and evaluating data. DPR would consult with the water boards or Department of Fish and Game staff, as appropriate, on the development of regulations.

PROTECT UNIQUE PEST PROTECTION PROGRAMS

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that the U.S. EPA must register all pesticides sold or distributed in the U.S. Registration is dependent on proof obtained from scientific studies that show that pesticides can be used without posing unreasonable risks to people or the environment. When a pesticide is registered it clearly specifies on the label the allowable uses of the pesticide and the labeled rate of application. To complete a full registration or Section 3 can take years.

There are certain cases where it is impractical or impossible to take the time necessary to apply for a full registration Section 3. Emergency conditions can arise due to a change in normal growing conditions causing unusual disease or pest pressure. An example is the 2003 wheat production that was hit extraordinarily hard by rust, a fungus that drastically reduces yields. Minor or specialty crop production often requires a much lower volume of pesticides making it economically impractical for chemical manufacturers to register pesticides for their use as it costs many thousands of dollars to produce the data required for a section 3 registration. A Section 18 Emergency Exemption or Section 24(c), Special Local Need (SLN) can address these situations as outlined below.

Section 18 allows state and federal agencies to apply to EPA for an exemption allowing an unregistered use of a pesticide to address an emergency condition. Exemptions may be granted for unregistered uses of registered pesticides or use of unregistered pesticides. The following criteria must be met when applying for a Section 18 exemption:

- No tolerance yet established. U.S. EPA will establish a time limited tolerance.
- Emergency situation must be documented – not a historical pest problem. Verification of economic loss and lack of alternatives must be documented.
- Data required - residue, efficacy, and phytotoxicity.
- Scientific evaluation.
- Letter of authorization from manufacturer.
- Post for comment although not technically required.
- Write justification to U.S. EPA and wait for approval that includes the use, limitations on acreage and location and the time-limited tolerance.
- Expiration date not to exceed one year.
- Must be third party.
- No U.S. EPA maintenance fees.

Section 24(c) grants states the authority to register additional or new uses of federally registered pesticide products to meet special local needs within a state.

Local needs registration applies only to states and is granted only for pesticide products that contain federally registered active ingredients. The following criteria must be met when applying for a Section 24(c):

- Tolerance or exemption already established.
- Justification and lack of alternatives must be documented.
- Data required – residue, efficacy, phytotoxicity.
- Scientific evaluation.
- Letter of authorization from manufacturer.
- Post for comment.
- Issued without expiration date, although can be inactivated.
- May be third party or first-party.
- Must pay U.S. EPA maintenance fees.

Whereas Section 18's and 24(c)'s provide a means to address problem situations it is still impossible to predict when an emergency situation will take place. The average time it takes to complete a Section 18 is three months. If the emergency is weather related there is no way to predict the condition far enough in advance to make it practical to apply and gain use in time to treat the problem.

For 24(c) SLN application, providing the required efficacy data often is problematic, again due to the use on specialty crops and lower overall acreage.

A. Support Emergency Exemptions ("Section 18"s) For Resistance Management and Other Needs of Production Agriculture, and Enhance Availability of Special Local Need Registrations ("Section 24c"s) Through Multiple Registrations.

1. On Section 18 registrations, decisions on whether or not an "emergency" exists should be made by CDFA rather than DPR, as CDFA has a more comprehensive knowledge of production practices and the economic impacts of not getting control of pests as soon as possible.

2. DPR should enhance the processing of Section 18 registration applications and expedite reviews due to the emergency nature of the pest infestation.

3. With regard to both Section 18 and Section 24 (c) registration activities, a more intensive and comprehensive training program for DPR personnel should be implemented to provide a better understanding and knowledge of agricultural production practices, plant pests, control and eradication methods and materials and the economic impacts of common agricultural pests.

4. It should be an objective of DPR to “facilitate” the registration of pest control, eradication and prevention products that are needed by agriculture and other users whenever possible and to avoid imposing unnecessary barriers to registration that play no role in protecting the health of workers, the public or the environment.

DPR AND USEPA PESTICIDE DATA REQUIREMENTS

PESTICIDES INTENDED FOR AGRICULTURAL USE
ON FOOD CROPS

Data Category	USEPA	DPR	DPR Basis[i]
Efficacy (Evaluates the effectiveness of the product)		X	Submission Not Required by USEPA Specific DPR Regulation: 6186
Crop Protection (Evaluates potential to damage treated crop)		X	Not required by USEPA Specific DPR Regulation: 6192(b)
Acute Toxicity (Evaluates effects of single exposure)	X	X	General DPR Regulation: 6159 Specific DPR Regulation: 6172(a)
Subchronic Toxicity (Evaluates short term seasonal exposures)	X	X	General DPR Regulation: 6159
Chronic Toxicity (Evaluates long term exposures, such as cancer)	X	X	Specific CA Statute: 13121 et seq. (SB-950) General DPR Regulation: 6159 Specific DPR Regulation: 6172(b)
Toxicity to Birds	X	X	General DPR Regulation: 6159
Toxicity to Fish and Aquatic Organisms	X	X	General DPR Regulation: 6159
Honeybee Toxicity (Beneficial Insects)	X	X	General DPR Regulation: 6159 Specific DPR Regulation: 6187
Product Chemistry	X	X	General DPR Regulation: 6159
Residues on Food (Used to estimate dietary exposure)	X	X	General DPR Regulation: 6159 Specific DPR Regulations: 6184, 6185
Environmental Fate (Evaluates pesticide behavior in water, air and soil)	X	X	Specific CA Statute: 13141 et seq. (AB-2021) General DPR Regulation: 6159 Specific DPR Regulation: 6192(c)(d)